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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/560,452 | 06/14/2006 | Andreas Lendlein | 26538-0016 | 3000 |

24633 7590 06/11/2010

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| EXAMINER | |
|---|---|
| MCEVOY, THOMAS M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3731 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 06/11/2010 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/560,452 | LENDLEIN ET AL. | |
| | Examiner | Art Unit | |
| | THOMAS MCEVOY | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *3,4,17-30,32,35 and 38-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,17-30,32,35 and 38-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 3, 4, 17, 28, 30, 32, 35 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (US 5,716,410).

Regarding claims 3 and 32, Wang et al. disclose a method of treatment of a patient needing a stent comprising the steps of:

(a) placing a stent onto a catheter selected from the group consisting of at least one of a temperature-controlled balloon catheter (col. 10, lines 10-15) and a balloon catheter equipped with a suitable light source, wherein the stent comprises a material selected from the group consisting of (i) a material consisting essentially of at least one non-metallic shape memory polymer (SMP) having at least one transition temperature

Ttrans (col. 6, lines 25-39) and (ii) a scaffold comprising a non-shape memory polymer that supports at least one material consisting essentially of at least one non-metallic SMP having at least one transition temperature $T_{trans}$, and wherein the stent exists in a permanent shape (col. 12, lines 36-37); (b) inserting the stent into a desired position; (c) heating the stent above the temperature $T_{trans}$ by means of the catheter; (d) expanding the stent to a temporary shape by means of the catheter; (e) cooling the expanded stent by means of the catheter below $T_{trans}$ or irradiating the stent with light of a suitable wavelength to fix the stent in a temporary shape; and (f) removing the catheter (b-e are effectively disclosed in col. 12, lines 25-45). Wang et al. do not specifically disclose using a temperature-controlled balloon catheter in the figure 17 embodiment but do disclose that this embodiment is intended to be heated by a non-attached means so that it is not necessary to provide a conductive wire throughout the stent structure (col. 10, lines 41-60 and col. 12, lines 34-37). It would have been obvious to one of ordinary skill in the art to have heated the above embodiment by a temperature-controlled balloon as an alternate means to inductive heating which accomplishes the same goal of eliminating the need for a conducting wire. Regarding claim 4, the non-metallic SMP can be a thermoplastic (col. 6, lines 25-39). Regarding claims 17 and 28, Wang et al. disclose that the SMP can be polylactide based (col. 11, lines 11-13). Regarding claim 30, the stent is selected from the group consisting of being at least one of extruded, coated, casted, spinned, weaved and combinations thereof (col. 8, lines 47-49). Regarding claims 35 and 38, Wang et al. disclose a method of treatment of a patient needing removal of a stent comprising the steps of:

(a) inserting a catheter into a stent portion, the catheter being selected from the group consisting of at least one of a temperature-controlled balloon catheter and a balloon catheter equipped with a suitable light source, wherein the stent comprises a material selected from the group consisting of (i) a material consisting essentially of at least one non-metallic shape memory polymer (SMP) having at least one transition temperature $T_{trans}$ and (ii) a scaffold comprising a non-shape memory polymer that supports at least one material consisting essentially of at least one non-metallic SMP having at least one transition temperature $T_{trans}$, and wherein the stent exists in an expanded temporary shape (addressed above in regard to claim 32). Wang et al. disclose steps c and e (col. 10, lines 41-60 and col. 12, lines 34-37) but fail to disclose the use of a balloon catheter to effect these steps. Wang et al. do disclose using a balloon to provide heat in order to initiate the shape memory response as an alternate means for any of their embodiments (col. 10, lines 10-15). Therefore, it would have been obvious to one of ordinary skill in the art to have used a balloon to provide the heat necessary to initiate the shape memory response for the above cited embodiments as an alternate means suggested by Wang et al. Regarding step e, it would have been obvious to one of ordinary skill in the art to have removed the stent using the balloon since the stent would bias itself onto the balloon when the balloon initiates the shape memory response. When the balloon is deflated, the stent would loose contact with the vessel wall and can then be regarded as "fixed" onto the balloon. Furthermore, deflation of the balloon would cause its surface to be less uniform and more likely to resist removal of the stent due to drag. Regarding claim 39, the at least one nonmetallic SMP is at least one of an SMP-containing

polymer network, a thermoplastic SMP material, an SMP-containing composite polymer material, an SMP- containing polymer blend and combinations thereof (col. 6, lines 25-39). Regarding claim 40, the SMP is selected from the group consisting of at least one of caprolacton units, pentadecalacton units, ethyleneglycol units, propyleneglycol units, lactic acid units, glycol acid units and combinations thereof (col. 11, lines 11-13).

4. Claims 18-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (US 5,716,410) in view of Langer et al. (US 6,388,043).

Regarding claims 18-27, Wang et al. discloses the invention substantially as claimed and described above except for the e-module of the SMP material, the reset fixation value of the SMP material, or the reset ratio of the SMP material. Langer et al. teach that it is desirable to provide SMP's for stents with the claimed properties at or near the claimed values (col. 6, lines 45-52; Table 13; Table 15 and elsewhere). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used an SMP material with the above limitations and the ranges as recited in the claims since at least some are directly taught by Langer et al. desirable for SMP's and furthermore, since it has been held that where the general conditions of a claim (as shown in Tables 13, 15 and elsewhere) are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, Applicant has not disclosed that the claimed values and ranges solve any stated problem, produce any unexpected results or are for any particular purpose other than the same purpose which the other SMP's in Applicant's disclosure serve (unless Applicant is stating that all the disclosed SMP's posses these

properties in the claimed amounts). It appears that the invention would perform equally well if possessing the claimed properties in amounts outside the claimed values and ranges. Applicant has disclosed that any SMP is suitable for use with their invention (paragraph 0113 of Applicant's pre-grant publication) and has not disclosed how or why the specific materials with the claimed values and ranges would perform better for the intended use. Applicant has also disclosed that all the polymer networks of their invention (including those disclosed as known in the prior art) have greater than 90% reset fixation values (paragraph 0147 of Applicant's pre-grant publication). Therefore, it would have been an obvious matter of design choice to use SMP's with these values and ranges in constructing the stent of Wang et al. Regarding claim 29, Langer et al. disclose that an SMP can be made from cross-linked caprolactonemacromonomers (col. 4, lines 42-45). It would have been obvious to one of ordinary skill in the art in view of Langer et al. to have used cross-linked caprolactonemacromonomers to construct the stent of Wang et al. since Wang et al. effectively disclose that any thermoplastic SMP may be used for their invention (col. 10, lines 60-63).

### *Response to Arguments*

5. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

### *Conclusion*

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas Mcevoy/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
6/7/10